text as (c)(1) and adding paragraph (c)(2).

§ 180.368 [Corrected]

■ 3. On pages 51637 and 51638, in the third and first columns respectively, in the table to § 180.368 (a)(3), remove the stars wherever they appear.

[FR Doc. 05–22609 Filed 11–15–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0270; FRL–7740–1]

Sulfosulfuron; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of sulfosulfuron and its metabolites in or on Bahiagrass, forage; Bahiagrass, hay; Bermudagrass, forage; Bermudagrass, hay; milk; fat (of cattle, goat, horse and sheep); meat (of cattle, goat, horse and sheep); and meat byproducts (of cattle, goat, horse and sheep). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on Bahiagrass and Bermudagrass pastures and hayfields. This regulation establishes maximum permissible levels for residues of sulfosulfuron in these food commodities. The tolerances will expire and are revoked on December 31, 2009.

DATES: This regulation is effective November 16, 2005. Objections and requests for hearings must be received on or before January 17, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0270. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *pemberton.libby@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of This Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the herbicide sulfosulfuron, [1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine (calculated as sulfosulfuron), in or on Bahiagrass, forage at 11 parts per million (ppm); Bahiagrass, hay at 40 ppm; Bermudagrass, forage at 11 ppm; Bermudagrass, hay at 40 ppm; milk at 0.02 ppm; fat (of cattle, goat, horse and sheep) at 0.04 ppm; meat (of cattle, goat, horse and sheep) at 0.02 ppm; and meat byproducts (cattle, goat, horse and sheep) at 0.50 ppm. These tolerances will expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and

children from aggregate exposure to the pesticide chemical residue. . ..''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Sulfosulfuron on Bahia and Bermudagrass Pastures and Hayfields and FFDCA Tolerances

Alabama, Georgia, Louisiana, Mississippi and Oklahoma indicate that, with the removal of imazapic from the hay and pasture market, there is no available control for Johnsongrass in Bahiagrass and/or Bermudagrass pasture and hayfields. Growers may experience significant losses without sulfosulfuron to control Johnsongrass. Johnsongrass reduces Bermudagrass hay quality and value. Additionally, under stressful conditions such as drought, frost or trampling, Johnsongrass may produce prussic acid which is toxic to livestock. Imazapic, the herbicide previously used to control Johnsongrass, was removed from the pasture and hay market in January 2004 resulting in the need for an emergency replacement. EPA has authorized under FIFRA section 18 the use of sulfosulfuron on Bahiagrass and Bermudagrass pasture and hayfields for control of Johnsongrass in Alabama, Georgia, Louisiana, Mississippi, and Oklahoma. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of sulfosulfuron in or on forage and hay associated with both Bermudagrass and Bahiagrass, as well as on various animal commodities for which residues may be present. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on forage and hay associated with both Bermudagrass and Bahiagrass, as well as on the various associated animal commodities after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sulfosulfuron meets EPA's registration requirements for use on Bermudagrass or Bahiagrass or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of sulfosulfuron by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Alabama, Georgia, Louisiana, Mississippi, and Oklahoma to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for sulfosulfuron, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of sulfosulfuron and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for combined residues of sulfosulfuron and its metabolites (calculated as sulfosulfuron) in or on Bahiagrass, forage at 11 ppm; Bahiagrass, hay at 40 ppm; Bermudagrass, forage at 11 ppm; Bermudagrass, hay at 40 ppm; milk at 0.02 ppm; fat (of cattle, goat, horse and sheep) at 0.04 ppm; meat (of cattle, goat, horse and sheep) at 0.02 ppm; and meat byproducts (cattle, goat, horse and sheep) at 0.50 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases

(e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for sulfosulfuron used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFOSULFURON FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Hazard and Exposure Based Special FQPA Safety Factor	Study and Toxicological Effects
Acute Dietary; all populations	A dose and endpoint was not selected for acute dietary risk assessment because there were no effects attributable to a single dose (exposure) in the oral toxicology studies including developmental toxicity studies in the rat and the rabbit and an acute neurotoxicity study in the rat.	NA	NA
Chronic Dietary all populations	NOAEL= 24 mg/kg/day UF[1] = 100 Chronic RfD = 0.24 mg/kg/day	FQPA SF = 1 cPAD = cRfD ÷ FQPA SF cPAD = 0.24 mg/kg/day	Chronic toxicity/carcinogenicity - rat; LOAEL = 244.2 mg/kg/day based on urinary tract pathology,abnormal cyrtals and urinary calculi (both sexes); mineraliztion in heart, lung, pancreas, and skeletal muscles (male)
Short-,Intermediate- Long-Term Dermal	No dermal or systemic toxicity was seen following repeated dermal application at the limit dose in a 21–day dermal toxicity study in rats. Therefore, this risk assessment is not required.	NA	NA
Inhalation (Any time period)	Based on the low acute inhalation toxicity (Category IV; no mortality at 3 mg/L), the formulation of the product as wettable granules, and the low application rates for the proposed use patterns ranging from 25 - 70 g a.i./hectare (10-28 g a.i./acre), there is minimal concern for potential inhalation exposure and risk. Therefore, a separate inhalation risk assessment is not required.	NA	NA
Cancer	Likely human carcinogen - Q1* = 1.03 x 10^{-3} $(mg/kg/day)^{-1}$ in human equivalents (converted from animals to humans by use of the $BW^{3/4}$'s scaling factor)	NA	NA

[1] uncertainty factor; 10x for intraspecies variation and 10x for interspecies variation
* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.552) for the combined residues of sulfosulfuron, in or on wheat grain, forage, hay, staw and related milk and meat commodities. Risk assessments were conducted by EPA to assess dietary exposures from sulfosulfuron in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. As summarized in Table 1 (above), EPA's review has concluded that sulfosulfuron has low acute oral, dermal, and inhalation toxicity. It is non-irritating to skin and slightly irritating to eyes. It is not a skin sensitizer. EPA has not selected toxicity endpoints for acute exposure reflecting the low hazard associated with acute exposure to this chemical.

ii. *Chronic exposure and cancer assessement.* Chronic and cancer dietary risk assessments were conducted using Lifeline™ (ver. 2.00) and the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 1.30) models. Both of these models use food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII); 1994–1996 and 1998).

The chronic and cancer analyses assumed tolerance level residues, 100% crop treated, and DEEM™ (ver. 7.76) default processing factors. The Lifeline™ chronic exposure estimates were <1% cPAD for all population subgroups (therefore less than EPA's level of concern). The Lifeline™ lifetime cancer risk for the U.S. population is 2.0 x 10^{-7} (therefore less than EPA's level of concern for the general U.S. population). DEEM-FCID™ resulted in chronic (<1% cPAD; children 1-2 years old were the most highly exposed subgroup) and cancer

(2.1×10^{-7}) exposure estimates similar to Lifeline™.

In accordance with the Agency's Proposed Guidelines for Carcinogenic Risk Assessment (April 10, 1996), EPA has classified sulfosulfuron as a likely human carcinogen. The weight-of-evidence for this classification includes: (1) Occurrence of rare transitional cell papilloma (benign tumors) and carcinoma of the urinary bladder in female rats; (2) occurrence of rare benign mesenchymal tumors of the urinary bladder in high dose male as well as renal adenomas in female and possibly male mice, and (3) the relevancy of the observed tumors to human exposure.

EPA utilizes a linear low-dose approach (Q1*) for human risk characterization and extrapolation of risk should be based on the incidence of benign mesenchymal tumors in male mice. The rat transitional cell tumors and mouse renal adenomas were not used because of their low incidence. This extrapolation, rather than an MOE approach, is supported by the lack of sufficient data to characterize the mechanism of carcinogenicity. The unit risk, Q1* (in milligrams/kilograms/day) $(mg/kg/day)^{-1}$ of sulfosulfuron based upon male mouse urinary bladder mesenchymal tumor rates is 1.03×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents.

iii. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use PCT information in this assessment. As stated above, EPA has performed a conservative assessment utilizing an assumption of 100% crop treated, and 100% tolerance levels detected, for the associated commodities.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sulfosulfuron in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of sulfosulfuron.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC)or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to sulfosulfuron they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of sulfosulfuron for acute exposures are estimated to be 0.66 parts per billion (ppb) for surface water and 1.9 ppb for ground water. The EECs for chronic exposures are estimated to be 1.73 ppb for surface water and 0.295 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

There are no residential uses of sulfosulfuron that are expected to result in residential handler exposure. However, the commercial use of sulfosulfuron on residential and recreational turf may lead to post application exposure in individuals. EPA has performed a cancer risk assessment for adults and children based on post application residential exposure.

Cancer risk for residential adults was calculated based on high and low activity. For high-exposure activity, a Transfer Coefficient (Tc) of 1,000 cm^2/hr (1 hr) was used and for low-exposure activity, a Tc of 500 cm^2/hr (1 hr) was used.

EPA built several conservative assumptions into the assessment of residential cancer risk. These include using 50 years of exposure and an estimated 20% (default) of dislodgeable foliar residues (DFR) from the turf, which is derived from the maximum application rate. An average of 14 days of DFRs was used for this cancer assessment; this would be considered a 10% decrease each day (from dilution by rain, and mowing of the grass) of the 20% residue for at least 14 days, and then taking the mean value of this 14–day exposure.

The Lifetime Average Daily Dose (LADD) = 6.0×10^{-5} mg/kg/day for a Tc =1,000 cm^2/hr (high-exposure activity for 1 hour) and for a Tc = 500 cm^2/hr (low-exposure activity for 1 hour) is equal to 3.0×10^{-5} mg/kg/day.

The estimated cancer risk for adults on day zero, based on high-exposure activity for 1 hour (Tc =1,000 cm^2/hr) is estimated to be 1.2×10^{-7}. For low-exposure activity (Tc = 500 cm^2/hr), the risk is estimated to be 6.0×10^{-8}.

Although it is likely that toddlers would also be exposed to sulfosulfuron from incidental ingestion of grass, soil, or hand-to-mouth transfer, no relevant oral toxicological endpoints have been identified by EPA. Therefore, to address the short-term residential risk to children from incidental exposure, for the purposes of this assessment only, EPA used the NOAEL of 24mg/kg/day from the combined chronic toxicity/ carcinogenicity study in rats. This NOAEL is considered conservative and health protective for this assessment because it represents the lowest NOAEL in the most sensitive species (the basis for the cRfD).

Postapplication inhalation exposure is considered to be negligible. However, non-dietary, incidental ingestion of residues from treated turfgrass and ingestion of contaminated soil are possible.

As a conservative measure, the exposure and risk estimates for four residential exposure scenarios are assessed for the day of application (day zero) because it is assumed that toddlers could contact the lawn immediately after application. Chronic exposure is not expected (i.e., these activities are

not expected to occur continuously for more than 30 days).

Children's estimated risk from oral hand-to-mouth activities on treated lawns is estimated to result in a short-term MOE of 1,700. Children's estimated risk from oral object-to-mouth (turfgrass) from treated lawns is estimated to result in a short-term MOE of 6,800. Children's estimated risk from incidental ingestion of soil from treated lawns is estimated to result in a short-term MOE of 510,000. Since short-term MOEs are above 100, they do not exceed EPA's level of concern. Chronic or long-term exposure is not expected.

While considered unlikely, if a toddler were to experience exposure from all of these sources at the same time, the combined incidental oral exposure would be 0.018 mg/kg/day. This combined exposure results in an estimated MOE of 1,400, which does not exceed EPA's level of concern.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sulfosulfuron and any other substances and sulfosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfosulfuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental reproductive toxicity studies*. The results of the 2–generation reproduction and developmental toxicity studies indicated that sulfosulfuron is not a developmental or reproductive toxicant. The acute and subchronic neurotoxicity studies showed that sulfosulfuron is not neurotoxic. Sulfosulfuron is rapidly excreted, primarily unmetabolized. Excretion at low dose occurred primarily in the urine, whereas at high dose, a large percentage of the administered dose was excreted in the feces. Sulfosulfuron was not retained in tissues to any significant extent.

3. *Conclusion*. There is a complete toxicity data base for sulfosulfuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA has determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because the developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure. Any detectable residues in food or drinking water would be expected at low levels since application rates are low. There are currently no registered homeowner uses for sulfosulfuron. Finally, concern for post-application exposure to infants and children from commercial application of the pesticide is tempered by the low acute oral, dermal, and inhalation toxicity of this pesticide.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day)) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to sulfosulfuron in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of sulfosulfuron on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. As discussed earlier, sulfosulfuron has low acute oral, dermal, and inhalation toxicity. It is non-irritating to skin, slightly irritating to eyes and is not a skin sensitizer. Endpoints for risk assessment through exposure via the acute dietary, dermal, inhalation and incidental oral routes were not identified; therefore, acute, short- and intermediate-term dermal and inhalation risk were not concerns.

2. *Chronic risk*. Chronic and cancer aggregate risk assessments were performed for adults, while short-term and chronic aggregate risk assessments were performed for children. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfosulfuron from food will utilize <1% of the cPAD for all population subgroups, including infants and children, young children, young adults, females of childbearing age and for the overall U.S. population. Based the use

pattern, chronic residential exposure to residues of sulfosulfuron is not expected. In addition, despite the potential for chronic dietary exposure to sulfosulfuron in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of sulfosulfuron in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SULFOSULFURON

Population	cPAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Max Chronic Water Exposure[1] (mg/kg/day)	Ground Water EEC[2] (ppb)	Surface Water EEC[2] (ppb)	Chronic DWLOC[3] (ppb)
General U.S. population	NA	0.000206	0.24	NA	NA	8,400
NA	0.24	NA	NA	0.295	1.73	NA
All infants (<1 year old)	NA	0.000286	0.24	NA	NA	2,400
Children (1-2 years old)	NA	0.000900	0.24	NA	NA	2,400
Children (3-5 years old)	NA	0.000636	0.24	NA	NA	2,400
Children (6-12 years old)	NA	0.000387	0.24	NA	NA	2,400
Youth (13-19 years old)	NA	0.000182	0.24	NA	NA	7,200
Adults (20-49 years old)	NA	0.000124	0.24	NA	NA	8,400
Adults (50 + years old)	NA	0.000114	0.24	NA	NA	8,400
Females (13-49 years old)	NA	0.000123	0.24	NA	NA	7,200

[1] Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM (mg/kg/day); no res. exp.
[2] FIRST and SCI-GROW modeling EECs (Tier 1)
[3] DWLOC(μg/L) = (allowable water exposure (mg/kg/day) x body weight (kg) x 1,000 μg/mg) ÷ (water consumption (liters))

3. *Short-term risk*. The short-term aggregate risk takes into account the exposure from potential residential sources in addition to average dietary residues from food and drinking water. The short-term aggregate risk assessment was performed for children only, since an endpoint for dermal risk assessment was not identified. The resulting short-term DWLOC is 2,200 ppb and is not of concern because it exceeds the EECs for sulfosulfuron. Short-term aggregate risks are presented in the following Table 3:

TABLE 3.—SHORT-TERM AGGREGATE RISK AND DWLOC CALCULATIONS

Population	Short-Term Scenario									
	NOAEL mg/kg/day	Target MOE	Max Exposure mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure mg/kg/day	Aggregate MOE (food and residential)	Allowable Water Exposure mg/kg/day	Ground Water EEC (ppb)	Surface Water EEC (ppb)	Short-Term DWLOC (ppb)
Child	24	100	0.24	0.00090	0.018	1,270	0.221100	0.295	1.73	2,200

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Although residential exposure could occur with the use of sulfosulfuron, no toxicological effects have been identified for intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. The cancer aggregate risk assessment considered exposure from food, water and residential sources. EPA performs cancer assessments for only the general U.S. population. The cancer dietary analyses assumed tolerance level residues, 100% crop treated, and DEEM default processing factors. The Lifeline™ lifetime cancer risk for the U.S. population is 2.0×10^{-7} and is therefore less than EPA's level of concern. Residential cancer risk was estimated for adults only. The aggregate cancer risk DWLOC of 25 ppb exceeds EECs for sulfosulfuron and does not result in a concern.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to sulfosulfuron residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address:*residuemethods@epa.gov*.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits, for residues of sulfosulfuron in or on grasses. Therefore, harmonization is not an issue for this tolerance action.

C. Conditions

No conditions are placed on these time-limited tolerances.

VI. Conclusion

Therefore, tolerances are established for combined residues of sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine (calculated as sulfosulfuron), in or on Bermudagrass, forage at 11 ppm; Bermudagrass, hay at 40 ppm; Bahiagrass, forage at 11 ppm; Bahiagrass, hay at 40 ppm; milk at 0.02 ppm; fat (of cattle, goat, horse and sheep) at 0.04 ppm; meat (of cattle, goat, horse and sheep) at 0.02 ppm; and meat byproducts (cattle, goat, horse and sheep) at 0.50 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0270 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 17, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2.*Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0270, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the

requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 7, 2005.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.552 is amended by adding text to paragraph (b) to read as follows:

§ 180.552 Sulfosulfuron; pesticide tolerances.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the herbicide sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine (calculated as sulfosulfuron) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances will expire on the dates specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Bahiagrass, forage	11	12/31/09
Bahiagrass, hay	40	12/31/09
Bermudagrass, forage	11	12/31/09
Bermudagrass, hay	40	12/31/09
Cattle, fat	0.04	12/31/09
Cattle, meat	0.02	12/31/09
Cattle, meat by-products	0.50	12/31/09
Goat, fat	0.04	12/31/09
Goat, meat	0.02	12/31/09
Goat, meat by-products	0.50	12/31/09
Horse, fat	0.04	12/31/09
Horse, meat	0.02	12/31/09
Horse, meat by-products	0.50	12/31/09
Milk	0.02	12/31/09
Sheep, fat	0.04	12/31/09
Sheep, meat	0.02	12/31/09
Sheep, meat by-products	0.50	12/31/09

* * * * *

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Addition of White Abalone and the United States Distinct Vertebrate Population Segment of the Smalltooth Sawfish to the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the Fish and Wildlife Service (Service), are adding two marine taxa to the List of Endangered and Threatened Wildlife (List) in accordance with the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (Act). These two taxa are the white abalone (*Haliotis sorenseni*) and the United States Distinct Vertebrate Population Segment (DPS) of the smalltooth sawfish (*Pristis pectinata*). These amendments are based on previously published determinations by the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Department of Commerce, which has jurisdiction for these species.

DATES: *Effective date:* This rule is effective November 16, 2005.

Applicability dates: The white abalone listing is applicable as of June 28, 2001. The United States DPS of the